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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13
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Applicants : Alexander Gad
and Dora Lis

Examiner: A. De Cloux

U.S. Serial No.: 09/816,989

Group Art Unit: 1644

Filed : March 23, 2001

For : COPOLYMER 1 RELATED POLYPEPTIDES FOR USE AS
MOLECULAR WEIGHT MARKERS AND FOR THERAPEUTIC
USE

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August 23, 2002

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Assistant Commissioner for Patents
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**SUBMISSION OF SIGNED DECLARATION AND POWER OF ATTORNEY TO
SUPPLEMENT AUGUST 1, 2002 AMENDMENT AND SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §1.97(b)(3)**

On August 1, 2002, applicants submitted an Amendment in Response to July 1, 2002 Restriction Requirement which, in part, added a priority claim to the above-identified application. By this submission, applicants are supplementing the August 1, 2002 response by the submission of a signed Declaration and Power of Attorney which recites the priority claim added in the August 1, 2002 response. Accordingly, applicants transmit herewith as **Exhibit A** a Declaration and Power of Attorney in connection with the above-identified application signed by Alexander Gad and Dora Lis on August 1, 2002. In compliance with 37 C.F.R. §1.63, the Declaration refers to the applications's above-identified serial number and filing date.

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Supplemental Information Disclosure Statement

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following publications which are listed again on the attached Form PTO-1449 (Exhibit B) and copies of Reference Items 1-41 (Exhibits 1-38).

This Supplemental Information Disclosure Statement is being submitted before the issuance of a first Office Action on the merits in connection with the subject application. Accordingly, no fee is required and this Supplemental Information Disclosure Statement shall be considered pursuant to 37 C.F.R. §1.97(b)(3).

Applicants also point out that several of the listed references are counterparts of each other and are cumulative. Therefore, in accordance with 37 C.F.R. §1.98(c), a counterpart of a reference is identified after the cite to the reference, but a copy of only one of the counterparts is being provided. Applicants will provide the Examiner with copies of any reference upon request.

1. U.S. Patent No. 5,554,372, issued September 10, 1996 (Hunter et al.) (Exhibit 1);
2. U.S. Patent No. 5,583,031, issued December 10, 1996 (Stern) (Exhibit 2);
3. U.S. Patent No. 5,623,052, issued April 22, 1997 (McLean et al.) (Exhibit 3);
4. U.S. Patent No. 5,734,023, issued March 31, 1998 (Bishwajit et al.) (Exhibit 4);

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5. U.S. Patent No. 5,886,156, issued March 23, 1999 (McLean et al.) (Exhibit 5);
6. U.S. Serial No. 09/487,793, filed January 20, 2000 (Exhibit 6);
7. U.S. Serial No. 09/620,216, filed July 20, 2000 (Exhibit 7);
8. U.S. Serial No. 09/765,301. Applicants point out that this reference is a counterpart of PCT International Application No. PCT/US01/02118 (WO 01/93893) (Exhibit 13);
9. U.S. Serial No. 09/765,644. Applicants point out that this reference is a counterpart of PCT International Application No. PCT/US01/02117 (WO 01/52878) (Exhibit 12);
10. PCT International Application No. PCT/EP91/01420 (WO 92/02543), published February 20, 1992 (Gaeta et al.) (Exhibit 8);
11. PCT International Application No. PCT/US93/06249 (WO 94/03484), published February 17, 1994 (McLean et al.). Applicants point out that this reference is a counterpart of U.S. Patent No. 5,623,052 (Exhibit 3) and U.S. Patent No. 5,886,156 (Exhibit 5);
12. PCT International Application No. PCT/US94/05632 (WO 94/26774), published November 24, 1994 (Alexander et al.) (Exhibit 9);
13. PCT International Application No. PCT/US95/04121 (WO

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95/26980), published October 12, 1995 (Hackett et al.) (Exhibit 10);

14. PCT International Application No. PCT/US94/05697 (WO 95/31997), published November 30, 1995 (Reid et al.) (Exhibit 11);

15. PCT International Application No. PCT/US01/02117 (WO 01/52878), published July 26, 2001 (Eisenbach-Schwartz et al.) (Exhibit 12);

16. PCT International Application No. PCT/US01/02118 (WO 01/93893), published December 13, 2001 (Eisenbach-Schwartz et al.) (Exhibit 13);

17. Fridkis-Hareli et al., "Synthetic Peptides that Inhibit Binding of the Collagen Type II 261-273 Epitope to Rheumatoid Arthritis-Associated HLA-DR1 and DR4 Molecules and Collagen-Specific T-cell Responses", Database HCAPLUS on STN, Department of Clinical Immunology, Aarhus University Hospital, Aarhus, Denmark, HCAPLUS AN: 2000:455053, Human Immunology, 2000, 61(7): 640-650 (Abstract) (Exhibit 14);

18. Henry, Celia M., "Special Delivery", Chem. and Eng. News, Sept. 18, 2000, 49-54 (Exhibit 15);

19. Cazzato et al., "Treatment of Multiple Sclerosis. The Present and the Future. Study Group on Diagnosis and Therapy of Multiple Sclerosis", Database Medline on STN, Instituto do Clinica Neurologica, Universita, Trieste, Italy: Medline AN: 2000060325, Recent Progressi in

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Medicina, October 1999, 90(10): 538-544 (Abstract) (Exhibit 16);

20. Cohen, "Fundamental Immunology", Systemic Autoimmunity, 4th Ed., 1999, 1083 (Exhibit 17);

21. Fridkis-Hareli et al., "Binding of random copolymers of three amino acids to class II MHC molecules", Intl. Immunol., 1999, 11(5): 635-641 (Exhibit 18);

22. Kepsutlu et al., "Evaluation of Chitosan Used as an Excipient in Tablet Formulations", Database HCAPLUS on STN, Department of Pharmaceutical Technology, Gulhane Military Medical Academy, Ankara, 06018, Turkey, HCAPLUS AN: 1999: 590411, Acta. Pol. Pharm. 1999, 56(3): 27-235 (Abstract) (Exhibit 19);

23. Prat et al., "Lymphocyte Migration and Multiple Sclerosis: Relation with Disease Course and Therapy," Ann. Neurol., 1999, 46: 253-256 (Exhibit 20);

24. Li et al., "Glatiramer acetate blocks the activation of THP-1 cells by interferon- γ ", Eur. J. Pharmacol., 1998, 342: 303-310 (Exhibit 21);

25. Zisman et al., "Dichotomy between the T and the B cell epitopes of the synthetic polypeptide (T,G)-A--L", Eur. J. Immunol., 1994, 24(10): 2497-2505 (Abstract) (Exhibit 22);

26. Kropshofer et al., "Self-Peptides from Four HLA-DR Alleles Share Hydrophobic Anchor Residues Near the NH₂-Terminal

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Including Proline as a Stop Signal for Trimming", J. Immunol., 1993, 151: 4732-4742 (Exhibit 23);

27. Deeb et al., "Comparision of Freund's and Ribi adjuvants for inducing antibodies to the synthetic antigen (TG)-AL in rabbits", J. Immunol. Methods, 1992, 152(1): 105-113 (Abstract) (Exhibit 24);
28. Zisman et al., "Direct binding of a synthetic multichain polypeptide to Class II Major Histocompatibility Complex molecules on Antigen-Presenting Cells and stimulation of a specific T-cell line require processing of the polypeptide", Proc. Natl. Acad. Sci. USA, 1991, 88(21): 9732-9742 (Abstract) (Exhibit 25);
29. Matsunaga et al., "Complementation of Class II A alleles in the immune response to (Glu-Lys-Tyr) polymers", Yokohama Med. Bull., 1988, 39(1-2): 9-19 (Abstract) (Exhibit 26);
30. De Kruyff et al., "Analysis of T Cell Responses to Poly-L (GluLys) at the Clonal Level. I. Presence of Responsive Clones in Nonresponder Mice", Eur. J. Immunol., 1987, 17 (8): 1115-1120 (Abstract) (Exhibit 27);
31. Lai et al., "Complementation of Class II A alleles in the immune response to (GluLysTyr) polymers", Exp. Clin. Immunogenet., 1986, 3(1): 38-48 (Abstract) (Exhibit 28);
32. Lai et al., "Monoclonal T cell responses to two epitopes on a single immunogen controlled by two distinct genes", J. Immunol., 1986, 136(10): 3799-3804 (Abstract) (Exhibit 29);
33. Trannoy et al., "Epitope-specific regulation of the T cell

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- repertoire: carrier recognition in association with I-E or I-A does not influence the restriction of hapten-specific T cells", Eur. J. Immunol., 1985, 15(12): 1215-1221 (Abstract) (Exhibit 30);
34. Faló et al., "Analysis of antigen presentation by metabolically inactive accessory cells and their isolated membranes", Proc. Natl. Acad. Sci. USA, 1985, 82(19): 6647-6651 (Abstract) (Exhibit 31);
35. Babu et al., "Ir gene control of T and B Cell Responses to Determinants in (Glu Lys Ala) Terpolymer", J. Immunogenet., 1984, 11(3-4): 251-254 (Exhibit 32);
36. Babu et al., "Reevaluation of response patterns of nonresponder mice to GLPhe polymers", Immunogen., 1983, 18(1): 97-100 (Abstract) (Exhibit 33);
37. Herzenberg et al., "Lack of immune response gene control for induction of epitope-specific suppression by TGAL antigen", Nature, 1982, 295: 329-331 (Abstract) (Exhibit 34);
38. Baxevanis et al., "Genetic Control of T-Cell Proliferative Responses to Poly (Glu⁴⁰Ala⁶⁰) and Poly (Glu⁵⁴Lys³⁴Tyr¹⁵) Subregion-Specific Inhibition of the Responses with Monoclonal Ia Antibodies", Immunogenetics, 1980, 11: 617-628 (Exhibit 35);
39. Maurer et al., "Interpretations of immune responses of mice to poly(Glu60Lys40), its modified derivatives, and the terpolymers poly (Glu55Lys37Leu8) and poly (Glu56Lys37Ser7)", Clin. Immunol. Immunopathol., 1980,

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15(3): 344-356 (Abstract) (**Exhibit 36**);

40. Ju et al., "Idiotypic analysis of antibodies against the terpolymer L-glutamic acid 60-L-alanine30-L-tyrosine10 (GAT). IV. Induction of CGAT idiootype following immunization with various synthetic polymers containing glutamic acid and tyrosine", Eur. J. Immunol., 1979, 9(7): 553-560 (Abstract) (**Exhibit 37**); and

41. Schwartz et al., "Gene complementation in the T lymphocyte proliferative response to poly (Glu57Lys38Tyr5): Evidence for effects of polymer handling and gene dosage", J. Immunol., 1979, 123(1): 272-278 (Abstract) (**Exhibit 38**).

Applicants request that the Examiner review the publications and make them of record in the subject application.

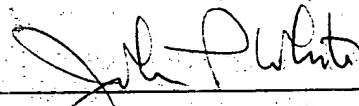
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Submission and Supplemental Information Disclosure Statement.

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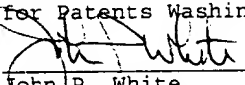
However, if any fee is required, authorization is hereby give to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231



8/23/02

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